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Michael Leavitt, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building (1101A)
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Washington, DC 20460

PETA
PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

HEADQUARTERS
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Re: Comments on the API's Test Plan for the Crude Oil Category

Dear Administrator Leavitt:

The following comments on the API's High Production Volume (HPV) test plan for the Crude Oil category are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

The API plans to conduct two combined reproductive/developmental tests (OECD 421) on a light crude oil and a heavy crude oil. These tests are unnecessary and duplicative of previous testing, do not take into account the existing information on these compounds, and violate both EPA and OECD guidance.

The API is violating both OECD and EPA guidance in proposing to conduct reproductive testing on substances for which it already has repeated dose data that includes an examination of reproductive organs and histopathology as well as developmental toxicity data. (See pp. 40-54, 60-69 of the robust summary and pp. 12-15 of the test plan.) The studies in the API's robust summary include characterization of effects of both light (Prudhoe) and heavy (Belridge) crudes, which is consistent with the proposed testing strategy of characterizing both heavy and light crude oils.

The EPA has clearly stated, for example in its comments on the HPV test plan for gamma-butyrolactone (http://www.epa.gov/chemrtk/gammabut/c14221tc.htm), that an "evaluation of reproduction organs from ... repeated-dose toxicity studies adequately address this [reproductive] endpoint." The OECD states in its Manual for Investigation of HPV Chemicals that when repeated dose studies which include the effects of reproductive organs and a developmental study are available, "the requirements for the reproduction toxicity endpoint would be satisfied" (Chapter 4).

Given the fact that many HPV sponsors (as just one example, see the BPPB Consortium's HPV test plan for 2- pyrrolidone) have followed this guidance, it is unclear whether the API is unaware of it or simply ignoring it. The robust summary of the crude oil category includes a 1992 repeated dose study for which standard protocols would have required the examination of the animals' reproductive organs. This information should be contained in the original report and the API needs to present the details of this aspect of the study. Together with the three "reliable" developmental toxicity studies included in the robust summary, the repeated-dose

information would clearly obviate the perceived need to kill yet another 1,300 animals in clearly painful experiments (crude oil was pumped directly into animals' stomachs).

There is absolutely no reason why a weight-of-evidence analysis of the developmental and repeated dose information cannot be used to meet the reproductive endpoint for the crude oil category. This is a scientifically valid analysis and adequate for a screening level program and is recommended by both the EPA and the OECD.

We have previously commented on similar plans submitted by the API, noting in particular the continuous nature of petroleum products (Petroleum coke, Lubricating oils, Waxes, Gasoline Category, Petroleum Napthas, Petroleum Gas). The common theme in all these plans is that the primary toxicity of these complex chemical mixtures is generally due to either specific compounds that are already well-characterized (e.g., BTEX or PAH compounds), or to the overall physical properties of the mixture as oily materials. The toxicity of these sorts of materials has been extensively studied both through animal testing and human exposure studies.[1,2,3,4] We have therefore disagreed with the proposed animal testing in all of the API's previous plans.

We must once again repeat our concerns and cite several specific categories that have very similar composition based on compounds derived from this source material. This test plan lays out this argument quite well:

> "There is a substantial body of data on products derived from crude oils, such as gasoline, diesel fuels, kerosene and jet fuels, lubricating oils and white oils, which are subjects of other HPV test plans. Extrapolation from these studies provides insight into biologically active components of crude oils. Occurrence and severity of toxic effects appear correlated with concentration of polynuclear aromatic hydrocarbons (PAH) and PAH-containing nitrogen or sulfur heteroatoms (PAC). In addition there are significant data developed from monitoring effects of unintentional oil spills, providing 'real world' environmental information."

Light saturate crude oils have many similar toxicological characteristics and contain the same toxic moeties as substances found in the API's previously proposed categories of gasoline blending streams and gas oils, as well as in the fuel oils, high benzene napthas, and low benzene napthas categories submitted by the ACC Olefins panel. The ACC found that there were sufficient data to preclude additional reproductive/developmental testing of these compounds.

Heavy crude oils share many similar toxicological characteristics and contain the same toxic moeties as substances found in the previously submitted API categories of lubricating basestocks, waxes, and gas oils, as well as in the higher olefins category proposed by the ACC Olefins Panel. The ACC provided abundant information that showed there was no need to conduct further reproductive/developmental testing on these compounds. These substances have all been thoroughly studied, are well-characterized including their reproductive and developmental effects, and there is an abundance of human exposure data on them as well. In short, an understanding of the toxicity of these specific compounds and of similar mixtures containing these compounds already exists.

While we are delighted that the API has identified a substance whose potential to kill fish is well enough understood that it does not plan to conduct further fish toxicity testing, we must ask the API, yet again, to undertake a thoughtful analysis of these materials and not condemn approximately 1,300 mammals to suffering and death in order to retest well-characterized compounds whose risks are already well understood and quantifiable.

I can be reached at 757-622-7382, ext. 8001, or via e-mail at JessicaS@peta.org should you have any questions.

Sincerely,

Jessica Sandler
Federal Agency Liaison

[1] ATSDR. 1995. Toxicological Profile For Polycyclic Aromatic Hydrocarbons (PAHs). Prepared By Research Triangle Institute for the U.S. Department Of Health And Human Services. Public Health Service

[2] ATSDR. 1999. Toxicological Profile For Total Petroleum Hydrocarbons (TPH). Prepared by Research Triangle Institute for the U.S. Department Of Health And Human Services Public Health Service.

[3] McKee, R.H. et al (1987b) Developmental toxicity of EDS recycle solvent and fuel oil. Toxicol 46, 205-215

[4] IPCS/WHO (1982) Environmental Health criteria 20: Selected petroleum products. Geneva: World Health Organization.